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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,620	11/26/2003	Richard J. Melker	UF-246XCD1	7104

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EXAMINER	
TURK, NEIL N	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,620	MELKER ET AL.	
	Examiner	Art Unit	
	NEIL TURK	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-27,29 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-27,29 and 30* is/are rejected.

7)☒ Claim(s) *1,2,4-27,29 and 30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Remarks

This Office Action fully acknowledges Applicant's remarks filed on February 7th, 2008. Claims 1, 2, 4-27, 29, and 30 are pending. Claims 3 and 28 have been cancelled.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 7th, 2008 has been entered.

Claim Objections

Claims 1, 2, 4-27, 29, and 30 are objected to because of the following informalities: there a multiple instances throughout the claims in which the term "odorous marker" is not used and "marker" only appears. Further, Examiner asserts all recitations with respect to the marker should recite "olfactory marker" so as to parallel Applicant's specification. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

> art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-27, 29, and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for providing a medication that itself comprises the detectable odorous marker, does not reasonably provide enablement for providing a combination of a medication and an odorous marker so as to detect the present/absence of the odorous marker to indicate compliance/non-compliance in taking the medication. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims. Applicant's method is directed toward detecting the presence of an odorous marker in a patient's breath in order to assess compliance/non-compliance in taking medication. Thereby, the odorous marker must be a part of the medication, otherwise no positive connection with the odorous marker can be made to the medication. The currently recited method is not operable in detecting if the medication has/has not been taken as it only tests if the odorous marker has/has not been taken.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4-27, 29, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: that the medication includes the odorous marker. As discussed above

with respect to the rejection of the claims under 112, 1st paragraph, the odorous marker must be included with the medication in order for the method to be operable for its purpose. Otherwise, there is no connection established to the presence/absence of the odorous marker and the medication being taken. Examiner notes that claims 2, 9, and 10 have such limitations.

Claims 1, 2, 4-27, 29, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation to "odorous markers" is unclear. Applicant's specification as disclosed in the pre-grant publication (US 2004/0081587) refers to the markers as olfactory markers, and the disclosure in the specification with respect to the term "odorous" refers to the detection of odorous substances. Even as olfactory markers can be said to be odorous markers, Examiner asserts that the recitation "odorous marker" in all instances of the claims should be changed to "olfactory marker" to parallel and coincide with Applicant's specification and thereby provide clarity to the claims.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how the recitation of claim 5 further limits the method of claim 1 (as well as claim 4). Claim 5 has a predisposed answer to the method of claim 1. Claim 5 recites that the marker is present.

Does Applicant intend to recite that the sensor technology is capable of producing a unique electronic fingerprint to characterize a marker, thus indicating the

presence (or absence) of the odorous marker in the patient's breath? If this is the case, Applicant must also establish a baseline or control odor response first so as to not mischaracterize natural odors of the patient's breath not associated with the marker administered with the medication. Examiner points to paragraphs [0030,0031] of the pre-grant publication US 2004/0081587 for such disclosure.

Claim 5 recites the limitation "the marker". There is insufficient antecedent basis for this limitation in the claim.

Claims 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how the recitations of the claim further limit the method of claim 1. Claims 23-25 all recite that the medication and marker are taken, thereby precluding the method of claim 1 as a predisposed answer of compliance has been recited. The second portion of the claim, which is made further unclear as the amended recitation, "and wherein" is awkward and unclear in its link to the previous portion of the claim. The second portion recites a capability to the odorous marker reacting in the mouth, stomach, or gastrointestinal tract and excreted in the lungs. As no further structure or specific marker has been recited, any odorous marker will be said to be capable to react/absorb as recited in the claims.

In claims 23-25, does Applicant intend to further limit the method by reciting different ways of providing the medication and marker to the patient? Such as providing it in a pill to be swallowed, an aerosol to be inhaled, a nasal spay to be taken in through the nostrils?

As currently recited, claims 23-25 do not further limit the method of claim 1 for at least the fact that the first portion of the claim pre-assumes the answer of compliance in taking the medication.

Claim 26 recites the limitation "the marker concentration". There is insufficient antecedent basis for this limitation in the claim.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how the patient's breath is analyzed to ascertain the concentration of the odorous marker. Claim 1 relates to a qualitative method of ascertaining a "yes" or "no" result with respect to the medication being taken or not based on the presence/absence of the odorous marker. Claim 1 or 26 also does not even recite that the patient's breath is sampled in any sort of tube or chamber. How is the quantitative analysis of the patient's breath performed? From Applicant's specification, it appears that the patient's breath is sampled within an electronic nose, wherein the change in resistance is transmitted to a processor to identify the type, quantity, and quality of the odor based on the pattern change in the sensor array. The unique response results in a distinct electrical fingerprint that is used to characterize the odor. The pattern of resistance changes of the array is diagnostic of the sample, while the amplitude of the pattern indicates the concentration of the sample (paragraph [0030], Applicant's pre-grant publication US 2004/0081587). Examiner further asserts that this claim limitation appears intended to be in conjunction with the type of recitation started in claim 5.

Claim 27 recites the limitation "the patient's taking of the medication". There is insufficient antecedent basis for this limitation in the claim.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation to, "prior to the patient's taking of the medication" is unclear. This recitation predisposes the answer to the recited method of claim 1. Does Applicant intend to recite, "prior to the patient being provided with the combination of the medication and odorous marker"?

Claims 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the medication combined with the detectable marker is produced. Claim 29 recites steps of identifying a marker substance detectable in gaseous breath and then producing a medication with said detectable marker substance. Applicant has not provided specific manufacturing steps for producing the combination of the medicine and the marker so as to be detectable and act as an indication of patient compliance. A general statement of producing the medication combined with the detectable marker will be read to constitute any production step(s) (or the final product is a medicine with a detectable marker, in which the production is inherent to arrive at the point) which results in a medicine with a detectable marker. Further, claim 30 does not further limit the method of producing the medication with further steps that provide for it being a transdermally delivered

medication, and thus such limitations are not afforded any patentable weight. Claim 30's recitation is drawn to an intended use.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 7-9, 12-21, and 23-27, 29, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Katzman (5,962,335).

Katzman discloses a breath test for detection of drug metabolism. Katzman discloses that a safe and effective amount of the drug, isotropically-labelled, is administered to a subject. Katzman discloses a breath test kit in which after a suitable amount of time the exhaled breath of the subject is analyzed to determine the concentration of a metabolite, which is then used to determine the rate of metabolism of the drug (abstract). Katzman also discloses that the exhaled breath of the subject is analyzed before the drug is administered so as to give a baseline for the concentration of the metabolite in the breath of the subject (lines 50-67, col. 5). Katzman also discloses that the label used to identify the metabolite in the exhaled breath of the subject should at least be present on a portion of the drug that forms the metabolite (columns 7 and 8; lines 22-26, col. 6). Katzman discloses that administrations include

such things as powders or granules, suspensions or solutions in water, capsules and tablets and flavorings. Examiner asserts that such flavorings would act as odorous markers whose presence or absence could be analyzed qualitatively as an indication of compliance or noncompliance in taking the drug. Katzman also discloses that the drug may be administered topically, such as intranasally, or parenterally such as by intravenous drip or intraperitoneal, subcutaneous, or intramuscular injection, or administration may be done inhalation (lines 43-67, col. 6). Katzman discloses that following the step of administering the drug to the subject, the exhaled breath of the subject is analyzed to detect a metabolite or metabolites, and subsequently the concentration of the metabolite is used to determine the rate of metabolism of the drug (lines 13-36, col. 7; col. 14). Katzman discloses that the metabolite or metabolites are detected by an instrument such as a gas analyzer, mass spectrometer, or infrared spectrometer (lines 21-36, col. 7; lines 38-40, col. 8). Katzman also discloses that the breath test could be used for therapeutic drug monitoring in determining the concentration of the metabolite(s) in the exhaled breath of the subject and using such information to properly adjust the dosing regimen for the subject (lines 58-67, col. 9; lines 1-2, col. 10). Examiner asserts that the acquisition of the two concentration measurements necessary for employing the difference between them to establish an acceptable dosage regimen would inherently constitute recording the two concentration measurements at their respective measurement steps.

Claims 1, 2, 6, and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Forester (4,762,719).

Forester discloses a cough drop comprising a hard candy outer shell and a powdered centerfill containing a rapidly-dissolving powder and an active ingredient such as menthol and eucalyptus which is in the form of a liquid blend and a spray-dried powder. Forester discloses that the hard candy outer shell also contains menthol and eucalyptus as a liquid blend (abstract). Forester discloses that the rapidly-dissolving powders used enhance active ingredient release to provide the aromatic vaporization of the ingredient into the oral and nasal cavities (lines 50-68, col. 1; column 3 and Example 3). Forester also discloses that the flavors which may be employed in the hard candy shell include both natural and synthetic flavors such as citrus oils of cherry, lemon, orange, and lime, or essential oils such as peppermint, spearmint, or wintergreen, and also synthetic flavors (lines 48-55, col. 2). Examiner asserts that smelling of the exhaled breath would confirm or deny the presence of the detectable marker, thus showing if the cough drop had been taken or not.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 5, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forester in view of Payne (WO 98/39470) and in view of Kell (5,652,146).

Forester has been discussed above.

Forester does not disclose analyzing the patient's breath to confirm the presence of the marker by either semiconductor gas sensor technology or conductive polymer gas sensor technology, nor by a spectrophotometer or a mass spectrometer.

Payne discloses a method of detecting conditions by analysis of gases or vapors. Payne discloses that the gas sensing device may comprise an array of semiconducting

organic polymer gas sensors and the presence of any species present in the gas phase may be detected (pages 1-3). Payne discloses that other types of gas sensors such as metal oxide semiconductor (MOS), quartz resonator or SAW devices, as well as mass spectrometry or a GC-MS device might be used (pages 3-5). Payne discloses that an array of such sensors are used so as to permit selective identification of a wide range of gases by recognizing the characteristic "fingerprint" of response across the array. Payne discloses that the output of the sensors correlates the output pattern (analyzed by analysis means 22) with the occurrence of certain conditions (page 4). Payne also discloses that it is possible to reduce water content by using purge and trap systems (page 6).

Kell discloses a method of monitoring patient compliance with medication prescriptions. Kell discloses that it is important to monitor a patient's regimen of medicine to ensure the medication is actually being taken as required (lines 11-16, 37-41, col. 1).

It would have been obvious to modify Forester to test to see that the medication is actually being taken such as taught by Kell as it is important to know if the necessary medication is actually being taken. Further, it would have been obvious to test the breath sample with semiconducting gas sensors, a spectrophotomer or a mass spectrometer to detect the presence of gases or vapors such as taught by Payne in order to provide dynamic sensing technology for gases or vapors that may produce a characteristic response to correlate a condition such as to show the presence or absence of the menthol (or possible flavor ingredient of Forester) in the patient's breath.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katzman in view of Payne.

Katzman does not specifically disclose analyzing the patient's breath to confirm the presence of the marker by either semiconductor gas sensor technology or conductive polymer gas sensor technology.

Katzman and Payne have been discussed above.

It would have been obvious to modify Katzman to test the breath sample with semiconducting gas sensors such as taught by Payne in order to provide dynamic sensing technology for gases or vapors that may produce a characteristic response to correlate a condition such as to show the presence or absence of the flavoring ingredient in the patient's breath.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Katzman in view of Forester.

Katzman and Forester have been discussed above.

Katzman does not specifically disclose a marker as listed in claim 6.

It would have been obvious to modify Katzman to include citrus or menthol such as taught by Forester such that Katzman discloses that flavorings may be desirable, and it would be obvious to modify Katzman to include citrus or menthol for the purpose of making the drug/medication more amenable and comfortable to be taken orally.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Forester in view of Payne and in view of Ueda.

Forester and Payne have been discussed above.

Forester and Payne do not specifically disclose dehumidifying the sample of the patient's breath prior to analysis.

Ueda discloses a method and device for expiratory air examination. Ueda teaches that an absorbing filter is provided for removing particulates and contaminants which would hinder the aimed examination. Ueda also discloses that a dehumidifying agent may be included partially in the absorbing filter (lines 11-62, col. 6).

It would have been obvious to modify Forester to include dehumidifying the air sample with a dehumidifying agent before analysis such as taught by Ueda so as to remove any moisture that may hinder the aimed examination and further given that Payne discloses a similar breath sampling method and device in which Payne teaches possibly including filters or reducing water content.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Katzman in view of Payne and in view of Ueda.

Katzman, Payne, and Ueda have been discussed above.

It would have been obvious to modify Katzman to include dehumidifying the air sample with a dehumidifying agent before analysis such as taught by Ueda so as to remove any moisture that may hinder the aimed examination and further given that Payne discloses a similar breath sampling method and device in which Payne teaches possibly including filters or reducing water content.

Response to Arguments

Applicant's arguments with respect to claims rejected under 35 USC 112, 2nd paragraph have been considered but are moot in view of the new ground(s) of rejection as discussed above.

Applicant's arguments filed February 7th, 2008 have been fully considered but they are not persuasive.

With respect to **claims 1, 2, 7-9, 12-21, and 23-27, 29, and 30** rejected under 35 USC 102(e) over Katzman, Applicant argues that Katzman does not asses a patient's breath for odorous compounds. Examiner argues that Katzman discloses using flavorings in the compositions used for oral administration and such flavorings would act as odorous markers detectable in the exhaled breath for the qualitiative assessment of an indication of compliance/non-compliance in taking the medicine. Examiner further asserts that Applicant has not established a specific chemical gas indicative of a particular odor, and thus any substance taken by the patient may be said to be "odorous" and thereby qualitatively detectable in the least. Examiner asserts that the detection of the exhaled breath in Katzman (including chemical flavorings, in both cases being "odorous" and detectable both qualitatively and more scientifically and quantifiably by gas analyzers, mass spectrometers, or spectrophotometers) is indicative of the drug being taken/not taken, given qualitative/quantitative measures of the flavoring being present/absent in the breath.

With respect **to claims 1, 2, 6, and 9-11** rejected under 35 USC 102(b) over Forester, Applicant argues that Forrester does not teach methods for monitoring patient compliance in taking medication. Examiner argues that Forester teaches a medication with an odorous marker, in which the steps of taking the medication and sampling the breath are implicitly recited as one would be able to detect exhaled breath from the living subject taking the cough drop, and thereby asses the presence/absence of the odorous marker of the cough drop.

With regards **to claims 4 and 5** rejected under 35 USC 103(a) over Forester in view of Payne and Kell, Applicant argues that the combination is improper. Examiner argues that no such deficiencies exist in Forester and that the disclosure of Kell was brought in for its recognizing the importance of monitoring patient compliance in taking medication, not for disclosure to urine analysis. Further, Payne discloses a known gas sensing semiconductor technology that can be used to show the presence or absence of the menthol (or flavor ingredient in Forester). The combination is maintained proper as previously discussed on the record.

With regard to claim 22 rejected under 35 USC 103(a) over Forester in view of Payne and Ueda, Applicant argues that the combination is improper. Examiner asserts that no such deficiencies exist in Forester and Payne, and thereby the combination of Forester in view of Payne and Ueda is maintained as previously discussed on the record.

With regard to claim 22 rejected under 35 USC 103(a) over Katzman in view of Payne and Ueda, Applicant argues that the combination is improper. Examiner asserts

that no such deficiencies exist and thereby the combination is maintained proper as previously discussed on the record.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT

/Jill A. Warden/
Supervisory Patent Examiner, Art Unit 1797